Title: Molecular Testing and Non-Small Cell Lung Cancer Patients – Improving Efficacy, Enhancing Care"

Background and Significance: Lung Cancer, the number one cancer killer in America, has been considered an aggressive, relentlessly progressive disease, with many patients diagnosed with advanced stage tumors and given few treatment options. Louisiana has the second highest rate of cancer among the States (Cancer Facts and Figures 2012, ACS), and a high rate of death from Lung Cancer.

To improve efficacy and enhance care for lung cancer patients, the Mary Bird Perkins – Our Lady of the Lake Cancer Center sustains an aggressive, holistic approach to program improvement, with the Lung Cancer Multidisciplinary Care Team providing leadership for high-quality, evidenced-based care. A focus on molecular testing to improve treatment for lung cancer patients is heavily aligned with both our mission and our dedication to improving patient care.

Purpose: Our project demonstrates a community hospital model for incorporating molecular testing, as recommended in national guidelines to expand the use of targeted therapies for non-small cell lung cancer (NSCLC) patients. With "Improving Efficacy, Enhancing Care", the Mary Bird Perkins – Our Lady of the Lake Cancer Center focuses ultimately on improving personalized medical treatment to extend survival of NSCLC patients, especially those with late stage disease or recurrence. To shift clinical practice to new standards of care for lung cancer, our project addresses the automation of system processes and enhanced clinician knowledge and competencies. The science is complex, however, and the optimum outcome for lung cancer patients may depend upon the collaboration of several physicians who are current on research, updated guidelines, the patient's history, and a detailed profile of the tumor.

Problem: Advances in drug development and genetic sequencing prompted dramatic shifts in cancer care, requiring clinicians to comprehend multiple options for quality tissue assessment and the impact of multiple tests on treatment decisions. Hospital communication among Surgeons, Pathologists, and Oncologists were paper intensive, laborious, and dependent on faxes and phone calls between physicians and the lab as multiple orders were often required for testing lung tissue samples for epidermal growth factor receptors (EGFR) and anaplastic lymphoma kinase (ALK)—with inconsistencies across the physician network in regard to molecular testing and targeted therapies as recommended in the latest guidelines for non-small cell lung cancer (NSCLC) from the National Comprehensive Cancer Network (NCCN)—the gold standard for cancer care.

Baseline chart audits of retrospective NSCLC patients (2011 and 2012), showed 28% compliance to research-based NCCN protocols. To fast track systemic shifts in evidence-based clinical practice that expanded the use of targeted therapies for NSCLC patients, we automated EMR "triggers", and enhanced pathology and tumor registry software as the framework for screening, tissue assessment, reporting, and clinical decision making. Expanding quality Continuing Medical Education (CME) improved clinical competence across multi-disciplinary physician networks. Physician adherence to NCCN guidelines improved to over 90% by the end of 2014, as measured by chart audits of active patients and documentation of project related enhancements to Tumor Registry Abstract records.

** ADD 1ˢᵗ PICTURE of graph showing chart audits of prospective patients for 2014**

Method

I. To improve clinical competencies in lung cancer standards of care across the professional, multidisciplinary physician network, from adequate tissue acquisition through diagnosis and treatment, by expanding access to high quality, professional education through approved Continuing Medical Education (CME) offerings, as well as through informal but structured learning opportunities addressing new standards for NSCLC care.

Continuing Medical Education (CME) offerings held in 2014 to improve clinical competence across multidisciplinary physician networks:

- **What is molecular testing, and how does it impact patient care in NSCLC** – presented by Dr. David Hanson, MD
- **The evolving role of the Pathologist in the diagnosis and treatment of NSCLC based on small biopsies/cytology samples –** presented by Dr. Anthony Harton, MD
- **Non-surgical lung biopsy: maximizing molecular yield in NSCLC** – presented by Dr. Brad Vincent, MD

II. To enhance existing technology as a structural framework for screening, tissue assessment, reporting, and clinical decision-making for NSCLC patient care compliance with the NCCN guidelines.

Automation of EMR "triggers" and enhanced pathology software – representative from LigoLab educated current Informatics Director of the Pathology Group of Louisiana and its Pathologists on how to create auto notification on all NSCLC specimens. Pop-ups were devised to alert Pathologists to include the phrase "molecular testing may be indicated" on all Surgical Pathology Reports.

** ADD all screen shots of Pathology software **

III. Demonstrate a minimum of 90 percent compliance with the NCCN guidelines for molecular testing (EGFR and ALK) for NSCLC patients treated at the Mary Bird Perkins – Our Lady of the Lake Cancer Center by the end of the project through chart audits in real-time utilizing new technology enhancements rather than manual, retrospective studies.

User defined fields created in Tumor Registry Abstracts – a representative from CNExT educated current abstractors on how to create user defined fields, and collect additional data in the CNExT cancer registry abstracting software.

This training involved:

- Assigning item identification numbers, item names, and data types
- Assigning level of new data fields (connected to patient, tumor, or hospital level)
- The process to create new codes and labels as the need arises to collect additional data

** ADD screen shot of Tumor Registry Abstract**

Results and Conclusion

Educational opportunities (CMEs), and the Implementation of automated "triggers" within the Pathology Software system (LigoLab), as well as the Tumor Registry software system (CNExT) has demonstrated the following observational and anecdotal benefits for the patient:

- State of the art software system upgrades with the ability to capture and notify practitioners of the need for molecular testing
- Increased Physician and Allied Health knowledge and competency of NSCLC tissue acquisition and personalized, targeted therapies
- Over 90 percent compliance to NCCN guidelines designating the use of therapies targeting specific biomarkers identified through multi-step biospecimens assessment
- Potential for life extension of late stage NSCLC patients

As a caveat to these positive outcomes, the ability to add future data enhancements to both software systems has been built to incorporate any additional data captures needed, not only within the NSCLC patient population, but all patient types throughout the Mary Bird Perkins – Our Lady of the Lake Cancer Center.

Citations

Kelleher, F. C., Solomon, B., and McArthur, G. A. (2012). Molecular Therapeutic Advances in personalized Therapy of Melanoma and Non-Small Cell Lung Cancer. *Journal of Personalized Medicine*, 35 – 49.

Philip Cagle, M. F. (2010). Molecular Diagnosis for Lung Cancer. *College of American Pathologists*, 1-78.